



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY;;;  
WASHINGTON, D.C. 20460

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2006 APR 18 AM 8:00

201-16235

APR 11 2006

Mr. Sam Ghantous  
Director of Operations  
PMC Specialties Group, Inc.  
501 Murray Road  
Cincinnati, OH 45217-1014

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Dear Mr. Ghantous:

Thank you for your letter dated December 29, 2005, to the Administrator, U. S. Environmental Protection Agency (EPA), regarding EPA's High Production Volume (HPV) Challenge Program. In your letter, you discussed difficulties regarding the continued sponsorship of CAS No. 134-20-3 by PMC Specialties Group, Inc. (PMCSG) within the Challenge Program as well as your ongoing objections to the inclusion of this chemical on the HPV Challenge Program Chemical List. Your company and its subsidiary, Cincinnati Specialties, Inc., have presented arguments regarding the latter issue to EPA in the past. The Agency will address both of these matters in our reply.

First, you indicated in your letter that PMCSG is presently unable to undertake the data gathering and data generation steps required for honoring your commitment for CAS No. 134-20-3 under the HPV Challenge Program due to economic conditions, primarily competition from foreign producers of your products. Since PMCSG is the only domestic manufacturer of CAS No. 134-20-3, you stated that your company would be at a competitive disadvantage in relation to foreign competitors if PMCSG were to undertake alone the costs of compiling existing data and conducting new testing for this chemical under the U.S. program. In addition, you said that you would be at a further disadvantage since no safeguards exist under the HPV Challenge Program to protect your company from the subsequent free use of this chemical data by foreign competition once it is collected and publicly released. However, you did state that PMCSG is open to joining an international testing program where the cost of compiling existing data and conducting any new testing for CAS No. 134-20-3 could be shared by all international producers and importers.

EPA recognizes PMCSG's claim of financial concerns if your company were to fulfill your commitment to collect and submit information for CAS No. 134-20-3 under the U.S. HPV Challenge Program. If you are unable to participate in the Challenge Program due to such constraints and must therefore formally withdraw your commitment to sponsor this substance under the Program, please indicate this decision in a formal reply to EPA so that the Agency can appropriately document this sponsorship withdrawal. If PMCSG would like to participate in an international testing program, one option for your company is to nominate CAS No. 134-20-3 as a U.S. contribution to the Organization for Economic Cooperation and Development (OECD)

HPV Screening Information Data Set (SIDS) program. In this program, OECD member countries, along with the chemical industry, share the burden of collecting information, carrying out testing, and assessing the results for HPV chemicals that they produce or import in order to determine whether there is a need to undertake further work to clarify **and/or** manage the potential risks of these chemicals. A second option for participating in an international testing program is for PMCSG to become a sponsor of CAS No. 134-20-3 under the International Council of Chemical Associations (ICCA) HPV Initiative. In the ICCA HPV Initiative, prime responsibility for collecting hazard information and conducting any additional tests needed to supplement this information lies with the companies producing HPV chemicals. Companies either commit to lead the work for a specific HPV substance or category of substances or commit to co-sponsor the work through an international consortium, whereby members share the costs of data gathering, testing, and drafting hazard assessments. Please note that any HPV chemicals handled under the OECD HPV SIDS Program need not be addressed under the HPV Challenge Program and any chemicals sponsored under the ICCA HPV Initiative are considered to be sponsored in the Challenge Program.


In regards to your second issue, you stated that PMCSG has continued objections to the inclusion of CAS No. 134-20-3 on the HPV Challenge Program Chemical List, which is a matter you have raised to the Agency in the past. EPA has reviewed your present letter and all past correspondence with your company and its subsidiary, Cincinnati Specialties, Inc., concerning this matter. The Agency stands by its reply sent on November 18, 1999, regarding your initial request made on October 5, 1999, for the removal of CAS No. 134-20-3 from the HPV Challenge Program Chemical List. Specifically, EPA's policy continues to assert that if a chemical has been approved for use by another Federal agency or program this action does not in and of itself support an exemption for that substance **from** the HPV Challenge Program. The Agency's position continues to be that chemicals tested and approved by another Federal agency or program may contain data gaps in areas that may not be germane to other regulated uses (e.g., environmental fate and environmental toxicity), but that are germane to EPA concerns under the HPV Challenge Program. Furthermore, exposure scenarios may be different from those considered in a review by another Federal agency or program and may have the potential to cause adverse impacts on health or the environment. In addition, data supporting the regulated use of chemicals reviewed by other Federal agencies or programs may not be publicly available because of confidentiality claims. A manufacturer that submits data under one program, however, could submit that same information to EPA through the HPV Challenge Program in the form of robust summaries and thereby allow this data to become public.

If your company wishes to maintain your original commitment to sponsor and submit data for CAS No. 134-20-3 under the HPV Challenge Program, guidance on the development of robust summaries of pertinent hazard data and the submission of these summaries in adherence to Challenge Program procedures is available at [www.epa.gov/chemrtk/robsumgd.htm](http://www.epa.gov/chemrtk/robsumgd.htm). Providing these summaries along with the submission of other outlined components (i.e., full citations of published studies, any requested copies of unpublished studies, and a test plan) will allow EPA to consider your commitment for CAS No. 134-20-3 under the Challenge Program complete. Furthermore, please note that if CAS No. 134-20-3 is as well-tested as PMCSG contends, your analysis of existing data may indicate that no additional testing is required. In your test plan, you can present the existing data and make a case for its adequacy following the

guidelines posted at [www.epa.gov/chemrtk/datadfin.htm](http://www.epa.gov/chemrtk/datadfin.htm). If the data is considered adequate, PMCSG's sponsorship may be considered complete without any further chemical testing.

We will post your letter, accompanied by our reply, on the **ChemRTK website** as soon as possible. Should you have any questions pertaining to this response, please contact Diane Sheridan at (202) 564- 8176. If you have general questions concerning the HPV Challenge Program, please submit them through the **ChemRTK website** comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached via email at [tsc-hotline@epa.gov](mailto:tsc-hotline@epa.gov).

Sincerely,



Jim Willis, Director  
Chemical Control Division

cc: AR-201



501 Murray Road

Cincinnati, Ohio 45217-1014

Phone:

December 29, 2005

**CERTIFIED MAIL:** 70020860000445260985

Administrator  
U.S. Environmental Protection Agency  
P.O. box 1473  
Merrifield, Virginia 22 116

Attention: **Chemical** Right-to-Know Program

Re: HPV Challenge Program

Dear Administrator:

This is to acknowledge **PMC Specialties Group, Inc. (PMCSG)** receipt of your letter dated December 6, 2005 regarding the status of **PMCSG's HPV Challenge Program commitment for the following chemical:**

**CAS No.** 134-20-3 **Collective Index Name** Benzoic Acid, 2-amino, methyl ester

**134-20-3** **Benzoic Acid, 2-amino, methyl ester**

**Other Common Names:** **Methyl-2-Aminobenzoate**  
**Methyl Anthranilate**

In the past, PMCSG had presented its arguments and continues to do so regarding the inclusion of Methyl Anthranilate (MA, CAS **134-20-3**) on the HPV chemicals list. There seems to be little reason for this chemical to remain on the HPV Challenge Program list. Its safety has been thoroughly evaluated and documented by at least two other US agencies. In addition to its use as intermediate for food additive products, MA is used in food as artificial grape flavoring. MA is included in the list of "Substances Generally Recognized as Safe" under 21 CFR 182.60 and 21 CFR 582.60. Certainly the Federal Government has reviewed the safety of this material for use in food.

MA is also the active ingredient in the pesticide product "RejexIt" which is a bird aversion product. Its toxicity, environmental fate and other required parameters have been thoroughly scrutinized for MA to be approved as a pesticide. The federal regulations for pesticide chemicals list MA as "Exemption from Tolerance" in food (40 CFR 180).

The HPV Challenge Program encourages U.S. companies to support the listed chemicals that they produce, but offers no protection against the use of the compiled and newly developed data under the program from foreign competition. PMCSG, along with various industry groups, has repeatedly raised this issue to the U.S. EPA for consideration and resolution in the past few years but no action was taken.



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PMCSG is the only domestic manufacturer of MA and faces direct competition in the manufacture of this material from foreign competitors. Without some proprietary protection for the development of **the** required data, PMCSG is placed at a competitive disadvantage despite its desire to support U.S. EPA's efforts. Moreover, current economic conditions within the company, primarily **the** competition from foreign producers of its products, especially MA, prevents PMCSG from being able to undertake the data gathering and data generation requirement of the HPV Challenge Program.

PMCSG though remains open to joining any international testing program. We feel that the international testing program levels the playing field for all international producers / importers and competitors to share in the cost of compiling existing data, developing **the** testing plan and conducting any additional tests as needed for MA. In the meantime, If you have any questions on this matter, please feel **free** to contact me by mail or by phone at (5 13) 242-3300.

Sincerely,

Sam Ghantous  
**Director** of Operations  
PMC Specialties Group, Inc.

cc: Michael Buchanan  
PMC **RAD**  
HPV File'



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

NOV 18 1999

OFFICE OF  
PREVENTION, PESTICIDES AND  
TOXIC SUBSTANCES

Ms. Catherine B. Rice  
Manager, Regulatory Affairs  
Cincinnati Specialties, Inc.  
501 Murray Road  
Cincinnati, Ohio 45217-1014

Dear Ms. Rice:

Thank you for your interest in the High Production Volume (HPV) Challenge Program. I am responding to your two letters, both dated October 5, 1999, requesting the delisting of four chemicals from our HPV Challenge Program Chemical List.

In your first letter, you requested the removal of Anthranilic Acid, Methyl Ester or Methyl Anthranilate (MA) (CAS Number 134-20-3) from the HPV Chemical List, because the chemical is regulated by the US Food and Drug Administration (FDA) or another EPA Program and because you believe the chemical has low toxicological concerns. Your second letter requested the removal of three chemicals: 1,2 Benzisothiazolin-3-one 1, 1 dioxide or Saccharin (CAS Number 81-07-2); 1,2 Benzisothiazolin-3-one 1,1 dioxide or Sodium Saccharin (CAS Number 128-44-9); and 1,2 Benzisothiazolin-3-one 1,1 dioxide or Ammonium Saccharin (CAS Number 6381-61-9). Your rationale for removal was that these chemicals are already being addressed by the FDA. In both letters, you expressed concern for duplicative testing.

All four chemicals were listed on the TSCA inventory and were reported under TSCA's Inventory Update Rule (IUR), indicating that production for uses exist for the chemicals other than that as a food ingredient or as an active ingredient in bird repellents. The fact that a chemical substance has been approved by another Federal agency or program does not in and of itself support an exemption for that substance from the HPV Challenge Program. Although some of the chemicals on the HPV Challenge Program Chemical List have been approved by other Federal agencies for food additive, drug, or cosmetic uses, for example, there may be data gaps in areas which may not be germane to these other regulated uses (e.g., environmental fate and environmental toxicity) but which are germane to EPA concerns and are elements under the HPV Challenge Program.

In addition, exposure scenarios may be different from those considered in the review conducted by another Federal agency (e.g., occupational exposures in industrial manufacture or use, or releases of the chemicals to the environment from industrial manufacturing sites), and may have the potential to cause adverse impacts on health or the environment. Furthermore, the data supporting the regulated use of chemicals reviewed by other Federal agencies may not be publicly



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available because of confidentiality claims. A manufacturer that submitted data under one program, however, could submit that same information to the EPA through the HPV Challenge Program in the form of robust summaries, and thus allow it to become public.

For well-tested chemicals, companies may provide the information in a test plan with robust summaries of the existing data, which would indicate no testing is required. In so doing, the company would get credit for sponsoring the chemical in the HPV Challenge Program. They could also nominate it as a U.S. contribution for the Organization for Economic Cooperation and Development (OECD) HPV Screening Information Data Set (SIDS) program to obtain international recognition of the hazard assessment prepared for that purpose. Alternatively, the chemical could be sponsored under the International Council of Chemical Associations (ICCA) HPV initiative ([www.icca-chem.org/hpv](http://www.icca-chem.org/hpv)) for international recognition under the SIDS Program as well.

Concerning methyl anthranilate (MA), which you state in your letter has low toxicological concerns, you may wish to consider supplying a technical rationale to the Agency which supports assigning an indicator of "1" to MA. Chemicals which have been assigned an indicator of "1" on the HPV Challenge Program Chemical List, are those which are not considered candidates for testing under the HPV Challenge Program, based on a preliminary EPA review indicating that testing using the SIDS base set would not further the understanding of the chemical's properties. The technical rationale would take the form of a review of the available information which shows that, for a given chemical, conducting the SIDS battery of tests would not be of value in furthering our understanding of the chemical's properties, including physical/chemical, environmental fate, environmental toxicity and mammalian toxicity endpoints. Technical rationales should include information and references obtained directly from studies. These technical rationales will be posted on our Chemical Right-to-Know Web Site. Please review the Agency's "Guidance for Assessing Adequacy of Existing Data" ([www.epa.gov/chemrtk/dsaddfn.htm](http://www.epa.gov/chemrtk/dsaddfn.htm)) for details on what constitutes adequate data under the HPV Challenge Program. This document will serve as useful guidance for developing the above-mentioned technical rationales.

The Agency shares your concern that unnecessary and duplicative testing should be avoided and is actively encouraging companies to bring forward and assess existing data. This, in fact, is a key first step in the HPV Challenge Program, prior to consideration of conducting additional tests. In crafting their test plans, HPV manufacturers who have test data on their chemicals can present those data and make the case for their adequacy. EPA has developed guidance for data adequacy, and has also developed guidance for conducting literature searches in the HPV Challenge Program. This should ensure that all existing data are located.

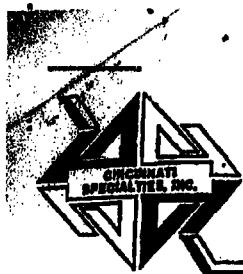
We realize that this response is arriving very close to the December 1, 1999 deadline for voluntary participation in the HPV Challenge Program. Given these circumstances, EPA will offer a 60-day grace period from the date of this letter during which your company may elect to sponsor these chemicals in the HPV Challenge Program, or submit a detailed rationale for their assignment of an indicator of "1," even though the December 1 deadline will have passed.

Please be advised that the Agency will post your letter, accompanied by this response, on the ChemRTK website approximately five days after mailing. If you have any questions concerning this response, please contact Barbara Leczynski, Chief of the Existing Chemicals Branch, at (202) 260-3943. If you have any general questions concerning the HPV Challenge Program, please submit them through the ChemRTK website comment button or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached through e-mail at [taca-hotline@epa.gov](mailto:taca-hotline@epa.gov).

We thank you for your letter and look forward to your participation in the HPV Challenge Program.

Sincerely,

Charles M. Auer, Director  
Chemical Control Division



501 Murray Road

Cincinnati, Ohio 45217-1014

Phone: (513) 242-3300

A SUBSIDIARY OF  
PMC SPECIALTIES GROUP, INC.

October \$1999

Mr. Charles **Auer**

**Office** of Pollution Prevention & **Toxics**

US Environmental Protection Agency (7405)

401 M Streets, SW

Washington, DC 20460

Reference: De-listing of an HPV chemical  
**Anthranilic** Acid, Methyl Ester or Methyl

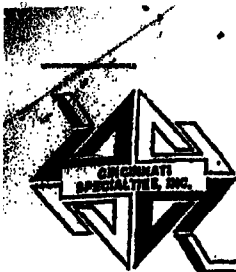
**Number** 134203)

Dear Mr. Auer:

Cincinnati Specialties, LLC is **respectfully** requesting that Methyl **Anthranilate** (MA) be de-listed from the High Production **Volume** (HPV) testing programs. This request is based on the following:

1. MA is a **naturally-occurring** biochemical that is recognized by the US Food and Drug Administration as being **Generally** Recognized as Safe (21 **CFR** 182.60) (refer to Attachment 1).
2. For over the past 20 years, MA has been used in foods at concentrations of **2200 ppm** (refer to Attachment 2).
3. Synthetic MA is a Food Grade Material that exceeds Food **Chemical Codex** Specifications (refer to Attachment 3).
4. MA is **currently** used as the active ingredient in several bird repellents that are registered by the US EPA (EPA Reg. No. **58035-8** for the active ingredient). Further, on April 26, 1995, the US EPA determined that MA was exempt from the requirements of a tolerance for blueberries, cherries, and grapes (60 FR **20432-20433**). To support these registration actions, extensive **chemical**, environmental, and **toxicological** testing has been on this chemical. This data has been submitted to and reviewed by the US EPA **Office of** Pesticide Programs (refer to Attachment 4 for a copy of the **label**, the exemption from **tolerance**, and a listing of the studies submitted).

Since MA is currently **regulated** by two Federal agencies, it appears that including it in the **HPV** testing program would be a duplication of efforts. Further, MA has **low** toxicological concerns as illustrated by the granting of the exemption from **tolerance**. For these reasons, we are



501 Murray Road

Cincinnati, Ohio 45217-1014

Phone: (513) 242-3300

A SUBSIDIARY OF  
PAC SPECIALTIES GROUP, INC.

October 5, 1999

Mr.  
Office of Pollution Prevention  
US Environmental Protection Agency (7405)  
401 M Streets, SW  
Washington, DC 20460

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2:08:59

Reference: **De-listing** of an HPV chemical  
**Anthranilic** Acid, Methyl Ester or Methyl **Anthranilate** (CAS Number 134203)

Dear Mr. Auer:

Cincinnati Specialties, LLC is **respectfully requesting** that *Methyl Anthranilate* (MA) be de-listed from the High Production Volume (HPV) testing programs. This request is based on the following:

1. MA is a **naturally-occurring** biochemical that is recognized by the **US** Food and Drug Administration as being **Generally** Recognized as Safe (21 CFR **182.60**) (refer to Attachment 1).
2. For over the past 20 years, MA has been used in foods at concentrations of 2200 **ppm** (refer to Attachment 2).
3. Synthetic MA is a Food Grade Material that exceeds Food Chemical Codex Specifications (refer to Attachment 3).
4. MA is **currently** used as the active **ingredient** in several bird **repellents** that **are** **registered** by the US EPA (EPA Reg. No. **58035-8** for the active ingredient). Further, on April **26, 1995**, the US EPA determined that MA was exempt from the requirements of a tolerance for **blueberries, cherries**, and grapes (60 FR **20432-20433**). To support these **registration** actions, extensive **chemical**, environmental, and **toxicological** testing has been on this chemical. This data has been submitted to and reviewed by the US EPA **Office of** Pesticide Programs (refer to Attachment 4 for a copy of the **label**, the exemption from tolerance, and a listing of the studies submitted).

Since MA is currently **regulated** by two Federal agencies, it appears that including it in the **HPV** testing program would be a duplication of efforts. Further, MA has concerns as illustrated by **the** granting of the exemption from **tolerance**. **For** these reasons, we are



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Second Edition

Volume 2

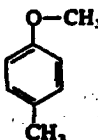
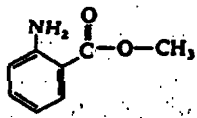
Edited, Translated, and Revised  
by  
**THOMAS E. FURIA and NICOLÓ BELLANCA**  
*Dynapol  
Palo Alto, California*

Adapted from the Italian language works of  
**PROF. DR. GIOVANNI FENAROLI**  
*Director, Center for Studies of Aromatic Substances  
University of Milano, Milano, Italy*

Published by



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	<i>p</i> -Methylamsole	Methyl anthranilate
Other names	<i>p</i> -Cresyl methyl ether <i>p</i> -Methoxy toluene Methyl <i>p</i> -cresol Methyl <i>p</i> -tolyl ether	Methyl 2-aminobenzoate Methyl <i>o</i> -aminobenzoate
Empirical formula	C <sub>8</sub> H <sub>10</sub> O	C <sub>8</sub> H <sub>9</sub> NO <sub>2</sub>
Structure		
Physical/chemical characteristics <sup>a</sup>		
Appearance	Colorless liquid	Colorless to pale-yellow liquid with bluish fluorescence
Assay		98% min <sup>2</sup>
Molecular weight	122.17	151.17
Melting point		24–25°C
Boiling point		132°C at 14 mm Hg
Congearing point		23.8°C (24°C)
Specific gravity	0.966–0.970 at 25°/25°C <sup>1</sup>	1.161–1.169 at 25°/25°C; <sup>2</sup> 1.1640 at 25°C
Refractive index	1.5100–1.5130 at 20°C <sup>2</sup>	1.5820–1.5840 at 20°C; <sup>2</sup> 1.5802 at 25°C
Cresol content	Not more than 0.5% <sup>1</sup>	
Solubility	1:3 in 80% alcohol; <sup>2</sup> soluble in most organic solvents; 1:7 in 70% alcohol	1:5 in 60% alcohol; <sup>2</sup> soluble in water and most organic solvents
Organoleptic characteristics	Pungent odor suggestive of ylang-ylang	Characteristic orange-flower odor, and slightly bitter, pungent taste
Synthesis	By methylation of <i>p</i> -cresol	By heating anthranilic acid and methyl alcohol in the presence of sulfuric acid and subsequent distillation
Natural occurrence	Reported found in the oils of ylang-ylang, cananga, and others	Reported found in several essential oils: neroli, orange, bergamot, lemon, mandarin, jasmine, tuberose, gardenia, champaca, ylang-ylang, and others; also in the juice and oil of <i>Vitis labrusca</i> <sup>6,7</sup>
Reported uses <sup>3</sup>	Non-alcoholic beverages 2.7 ppm Ice cream, ices, etc. 2.7 ppm Candy 4.8 ppm Baked goods 7.6 ppm Gelatins and puddings 0.50–4.0 ppm Condiments 2.0 ppm Syrups 8.0 ppm	Non-alcoholic beverages 16 ppm Alcoholic beverages 0.20 ppm Ice cream, ices, etc. 21 ppm Candy 56 ppm Baked goods 20 ppm Gelatins and puddings 23 ppm Chewing gum 2,200 ppm
Regulatory status	FDA 121.1164; FEMA No. 2681	FDA GRAS; FEMA No. 2682

## REFERENCES

For References 1–5, see end of Part III.

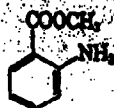
6. Mattick et al., *J. Agric. Food Chem.* 4, 334, 1963.
7. Roger, *Food Technol.*, 6, 309, 1961.

**Packaging and storage.** Store in full, tight, preferably glass, aluminum, tin-lined, or other suitably lined containers in a cool place protected from light.

**Functional use in foods.** Flavoring agent.

## METHYL ANTHRANILATE

Methyl 2-Aminobenzoate



$C_8H_9NO_2$

Mol. wt. 151.17

### DESCRIPTION

Methyl anthranilate is found in neroli oil and in citrus and other oils. It is prepared synthetically by esterification of anthranilic acid. It is a colorless to pale yellow liquid with a bluish fluorescence. It has a grape-like odor. It is soluble in most fixed oils and in propylene glycol, and is partly soluble in mineral oil. It is insoluble in glycerin.

### SPECIFICATIONS

**Assay.** Not less than 98.0 percent of  $C_8H_9NO_2$ .

**Refractive index.** Between 1.582 and 1.584 at 20°, in supercooled liquid form.

**Solidification point.** Not less than 23.8°.

**Solubility in alcohol.** Passes test.

**Specific gravity.** Between 1.161 and 1.169.

### TESTS

**Assay.** Weigh accurately about 1 gram, and proceed as directed under *Ester Determination*, page 896, using 75.59 as the equivalence factor (e) in the calculation.

**Refractive index, page 945.** Determine with an Abbé or other refractometer of equal or greater accuracy.

**Solidification point.** Determine as directed in the general method, page 954, supercooling the sample to 19° to 20°, but not below 18°, and seeding the melt to induce crystallization.

**Solubility in alcohol.** Proceed as directed in the general method, page 899. One ml. dissolves in 5 ml. of 60 percent alcohol, and remains in solution on dilution up to 10 ml. with the alcohol.

**Specific gravity.** Determine by any reliable method (see page 5).

(TSDs) available at EPA's Region IX office.

#### Response to Public Comments

The 30-day public comment periods were provided in 80 FR 6467 and 60 FR 7931. No comments were received.

#### EPA Action

EPA is finalizing action to approve the above rule for inclusion into the California SIP. EPA is approving the submittal under section 1109(k)(3) as meeting the requirements of section 110(a) and Part D of the CAA. This approval action will incorporate these rules into the federally approved SIP. The intended effect of approving these rules is to regulate emissions of VOCs in accordance with the requirements of the CAA.

Nothing in this action should be construed as permitting or allowing or establishing a precedent for any future request for revision to any state implementation plan. Each request for revision to the state implementation plan shall be considered separately in light of specific technical, economic, and environmental factors and in relation to relevant statutory and regulatory requirements.

#### Regulatory Process

The OMB has exempt this action from review under Executive Order 12866.

#### List of Subjects in 40 CFR Part 52

Environmental protection, Air pollution control, Hydrocarbons, Incorporation by reference, Intergovernmental relations, Ozone, Reporting and recordkeeping requirements, Volatile organic compounds.

Note: Incorporation by reference of the State Implementation Plan for the State of California was approved by the Director of the Federal Register on July 1, 1982.

Dated: March 29, 1995.

David P. Howekamp,  
Acting Regional Administrator.

Part 52, chapter I, title 40 of the Code of Federal Regulations is amended as follows:

#### PART 52—[AMENDED]

1. The authority citation for part 52 continues to read as follows:

Authority: 42 U.S.C. 7401-7871q.

#### Subpart F—California

2. Section 52.220 is amended by adding paragraph (c)(199)(i)(A)(2) to read as follows:

§ 52.220 Identification of plan.

(c) \* \* \*  
(199) \* \* \*  
(i) \* \* \*  
(A) \* \* \*

(2) Regulation 8, Rules 14 and 43 adopted on June 1, 1994, and regulation 8, Rules 13, 23, 47 adopted on June 15, 1994.

[FR Doc. 95-10250 Filed 4-25-95; 8:45 am]  
BILLING CODE 6560-50-M

#### 40 CFR Part 180

[PP 2E4071/R2117; FRL-4941-8]

RIN 2070-AB78

#### Methyl Anthranilate; Exemptions From the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** This document establishes an exemption from the requirement of a tolerance for residues of the biochemical methyl anthranilate in or on the raw agricultural commodities blueberry, cherry, and grape when the pesticide is used in accordance with good agricultural practices. The Interregional Research Project No. 4 (IR-4) requested this exemption in a petition submitted to EPA.

**EFFECTIVE DATE:** This regulation becomes effective April 26, 1995.

**ADDRESSES:** Written objections, identified by the document control number, [PP 2E4071/R2117], may be submitted to: Hearing Clerk (1900), Environmental Protection Agency, Rm. M3708, 401 M St., SW., Washington, DC 20460. A copy of any objections and hearing requests filed with the Hearing Clerk should be identified by the document control number and submitted to: Public Response and Program Resources Branch, Field Operations Division (7506C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. In person, bring copy of objections and hearing request to: Rm. 1132, CM #2, 1821 Jefferson Davis Hwy., Arlington, VA 22202. Fees accompanying objections shall be labeled "Tolerance Petition Fees" and forwarded to: EPA Headquarters Accounting Operations Branch, OPP (Tolerance Fees), P.O. Box 360277M, Pittsburgh, PA 15251.

**FOR FURTHER INFORMATION CONTACT:** By mail: Hoyt Jamerson, Registration Division (7506W), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington,

DC 20460. Office location and telephone number: Westfield Building North, 6th Fl., 2800 Crystal Drive, Arlington, VA 22202, (703)-308-8783; e-mail: Jamerson.Hoyt@epamail.epa.gov.

**SUPPLEMENTARY INFORMATION:** In the Federal Register of February 22, 1995 (60 FR 9816), EPA issued a proposed rule that gave notice that the Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, had submitted pesticide petition (PP) 2E4071 to EPA on behalf of the Agricultural Experiment Station of Washington. Pesticide petition 2E4071 requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. 348(e), establish exemptions from the requirement of a tolerance for residues of the biochemical methyl anthranilate in or on the raw agricultural commodities blueberry, cherry, and grape. Methyl anthranilate will be applied as a dilute foliar spray to these crops to control bird and insect damage. Methyl anthranilate is a natural constituent of food that can be found in grape and citrus. Methyl anthranilate is also synthetically produced and used in the purified form (not less than 99 percent pure) as a flavoring agent in beverages, ice cream, candy, baked goods, gelatins, puddings, and chewing gum. The synthetic product mimics the chemical structure and function of the natural plant constituent. Methyl anthranilate is listed by the Food and Drug Administration (FDA) as a flavoring compound under 21 CFR 102.50 and is classified generally recognized as safe (GRAS) by the Expert Panel of the Flavor and Extract Manufacturer's Association (FEMA). Residues who produce and use products for this active ingredient that are intended for use on blueberry, cherry, or grape will be required to use methyl anthranilate produced to meet or exceed U.S. Food Chemical Codex and U.S. Pharmacopoeia specifications.

There were no comments or requests for material to an advisory committee received in response to the proposed rule.

The data submitted relevant to the proposal and other relevant material have been evaluated and are consistent with the proposed rule. Based on the data and information considered, the Agency concludes that the tolerance exemption will protect the public health. Therefore, the tolerance exemption is established as set forth below.